PSJ10 Exh 60

New Jersey Pharmaceutical Industry Group

July 20, 2011

Mr. Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration
United States Department of Justice
8701 Morrissette Drive
Springfield, Virginia 22152

Dear Mr. Rannazzisi:

On behalf of the New Jersey Pharmaceutical Industry Group ("NJPIG")[1], we write to address the Drug Enforcement Administration's ("DEA" or "Agency") policies and procedures for processing initial and revised quota requests for controlled substances.

The NJPIG comprises companies registered by the DEA to engage in the manufacture and distribution of controlled substances in the State of New Jersey and selected manufacturers and distributors from contiguous or nearby states (i.e. Delaware, New York and Pennsylvania). The NJPIG was formed at the suggestion of Special Agent in Charge Gerard McAleer at his Pharmaceutical Industry Briefing (Medicine for Success) on February 27, 2008 at the Newark Field Office Conference/Training Room. During that briefing, which was attended by sixty-five (65) representatives of industry from the State of New Jersey, SAC McAleer stated that this was all about communication and collaboration, and he exhorted the attendees to "join us – be our partner". The SAC promised that the Newark Office would advocate for its industry partners with DEA Headquarters on matters of mutual interest.

The group generally meets twice per year, and as a reminder, you presented to the group on May 10, 2010 at Johnson and Johnson Headquarters in New Brunswick, New Jersey.

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[1] NJPIG consists of the following companies: Novartis Pharmaceuticals Corporation, Reckitt Benckiser Healthcare, Halo Pharmaceuticals, Purdue Pharma L.P., Johnson & Johnson, Noramco, Inc., Cephalon, Merck, Catalent, Covidien, Shire Pharmaceuticals, Sandoz, West-Ward Pharmaceuticals, Core Pharma, Watson Pharmaceuticals, Ranbaxy, Rhodes Technologies, Teva Pharmaceuticals, H.D. Smith, The P.F. Laboratories, Inc., Pfizer, Actavis USA, Barr Laboratories, Inc., Baxter, AmerisourceBergen, Roche, Stepan, Aptuit, Sun Pharma, Alpharma, JFC Technologies.

The NJPIG is eager to cooperate and work with the DEA to avoid disruption in the development and distribution of legitimate medicines to patients.

In light of the increasing concerns about the allocation of quotas and the delays in processing quota requests, NJPIG seeks clarification from DEA on the quota review process and the opportunity to discuss how the current process, and potential changes to that process, can and will adversely affect patient access.

Background

There are two concerns shared by NJPIG members with regard to DEA's process for establishing quotas: (1) DEA's reluctance to allocate sufficient quota in the initial established quota where adequate justification has been submitted on the DEA-189/250 forms, and (2) DEA's delay in issuing revised quotas. Due to DEA's limited initial establishment of quota, manufacturers routinely must submit multiple requests for increases in quota throughout the year. In many cases this is not due to changed demand, but rather as a result of DEA's limited allocation. This approach makes review of the subsequent applications that much more time sensitive and important.

In addition, more recently, Industry has experienced extended response times to requests for quota increases submitted to DEA's UN Reporting and Quota Section/ODQ. Prior to changes in the quota review process DEA has strived to achieve an average 30 business day cycle time; however in 2011 this has increased to 45 business days or 50% more time as a result of the additional departmental reviews outside ODQ. As a consequence, quota requests now may take as long as 9 weeks or more. We have been advised that the additional time is due to a new interpretation that the current regulations do not support the review/sign off process to be solely within the authority of ODQ and therefore additional time is necessary to allow for departmental reviews outside the ODQ group to include (but not limited to): Registration, Suspicious Order Monitoring and potentially other DEA staff to address special issues, as well as final review by the Office of Chief Counsel.

As you can appreciate, any delay is a potential hindrance to industry to provide for an uninterrupted supply of medication to healthcare providers. While DEA recently rolled-out its new on-line quota application process as a vehicle to streamline this process and improve review times, the inclusion of additional departmental reviews has negatively impacted this process improvement.

While NJPIG appreciates and fully supports DEA's need to ensure that the amount of quota allocated is consistent with legitimate use, the DEA's current process, and any

changes that would cause further delays in review of initial and revised quota requests causes significant hardship for us and affects our ability to meet legitimate patient needs.

Impact of Delays on Maintaining Adequate Supply

Members of the NJPIG are concerned about the longer review time for quota requests directly impacting the availability of medicine. If third-quarter quota requests are delayed manufacturers will have difficulty building up sufficient year-end inventory to support first quarter customer shipments in 2012, which may result in shortages / stock outs. This could impact patients and their ability to receive medicine in a timely fashion. DEA's delay in issuing initial and revised quotas may affect members' ability to launch new products. In addition, since dosage form development requires quota, delays with these requests hinders companies' ability to meet deadlines for such work. Quota allocations are needed to manufacture batches for formulation development, submission/testing, validation and launch.

Recommendations

We understand that the DEA's methodology for setting manufacturing and procurement quotas must balance its mandate to limit diversion and abuse with the medical need to ensure adequate availability of product supply for FDA-approved products, which includes product for research, development and clinical trials; new product testing, launch and adequate reserve inventory. We seek to obtain greater transparency in this process and work together to attempt to achieve these goals in the most expeditious time frame possible. We are requesting an opportunity to meet with DEA to discuss some possible steps that may increase the efficiency of the regulatory and administrative review process.

Some possible steps include:

- Continuing the recent trend of granting a sufficient initial established quota to manufacturers to meet foreseeable need during the year will reduce the frequency of requests for quota adjustments;
- Increase the inventory allowance in the event the current review process of 9 weeks cannot revert back to the historical 6 weeks in the short-term.
- A timely process for setting and revising aggregate quotas that provides manufacturers time to obtain and utilize the quota grants; consider revising the regulations to include deadlines within DEA from receipt of comments/objections to the final publication in the Federal Register.

- Establishing initial aggregate production quotas that allow for flexibility in supply, i.e., for new products/indications, launches and changes in manufacturing sites/suppliers, inventory needs, safety stock, lot failures, research and development, etc);
- DEA committing to a defined time-period to process requests for increases in quota; conceivably separate review cycles for commercial and non-commercial.
- Ability for DEA to promptly increase quota to account for contingencies and unforeseen circumstances.

In light of the upcoming proposed increase in the DEA registration fees, would it be feasible for a portion of this increase to be allocated to provide additional support for review and processing of quota requests?

If in fact there will be an additional time period for review of quota requests for the immediate future, we would request that DEA consider providing additional allowed year end stock to absorb the impact of the longer quota processing time. This would enable Industry to maintain the pipeline while allowing DEA time to manage/change the review process.

In conclusion, there is a considerable need to address this situation to ensure patient access to necessary medicine. We request the opportunity to meet at DEA Headquarters to address this important issue at the earliest opportunity.
We recognize that DEA is trying to achieve a balance, and seek to be part of a dialogue to ensure the quota process includes necessary controls while still providing adequate allocations when issuing initial quotas and adhering to a reasonable time-frame to review and process requests for increases during the year.

Please do not hesitate to contact any of us should you have any questions.

Sincerely,

The NJPIG Committee

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